IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
TANZI *et al.*
Appl. No. 10/052,817
Filed: January 23, 2002
For: **Alpha-2-Macroglobulin Therapies and Drug Screening Methods for Alzheimer's Disease**

Confirmation No.: 4182
Art Unit: 1632
Examiner: Woitach, J.
Atty. Docket: 0609.4460005/TJS/FRC

Reply to Restriction Requirement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated **April 28, 2004**, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of group II, represented by claims 2-10, 12, 13 and 27-29.

This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. This election is made **with** traverse.

The restriction requirement is improper, especially with respect to the division of claims 2-10, 12, 13 and 27-29 into groups I, II and III. The restriction requirement is improper because it divides *individual claims* into multiple groups. Claims 2-10, 12, 13 and 27-29 are directed to anti-LRP-Aβ molecules comprising an Aβ binding domain and an LRP binding domain, and to pharmaceutical compositions comprising the anti-LRP-Aβ

molecules. Claims 2-10, 12, 13 and 27-29 do not include any limitation as to the function(s) or properties exhibited by the anti-LRP-Aβ molecules.

The Examiner, however has divided claims 2-10, 12, 13 and 27-29 into three groups based on function: group I, specifying that the molecule can replace α_2M function; group II, specifying that the molecule can supplement α_2M function; and group III, specifying that the molecule can suppress expression of A2M-2. *There is no group that contains the entire scope of subject matter encompassed by claims 2-10, 12, 13 and 27-29*; *i.e.*, there is no group that encompasses an anti-LRP-Aβ molecule that is not limited by its function. This is a legally improper restriction requirement. Restriction practice cannot be applied to a single claim. *See In re Weber*, 198 USPQ 328 (CCPA 1978) and its companion case, *In re Haas*, 198 USPQ 334 (CCPA 1978).

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. *If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.* The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Weber at 331 (emphasis added).

It is clear that 35 U.S.C. § 121 does not grant to the PTO the authority to refuse to examine a single claimed invention. Section 121 only applies to plural claimed inventions in

different claims, wherein the different claims vary not just in scope, but in the invention to which each is directed. The division of claims 2-10, 12, 13 and 27-29 into groups I, II and III, without defining at least one group which contains the entire scope of subject matter encompassed by these claims is legally improper.

In addition, with respect to the claims of groups I and II, Applicants note that whether an anti-LRP-Aβ molecule "replaces α_2M function" or "supplements α_2M function" is not due to the properties of the molecule itself, but to the nature of the patient to whom the molecule is administered. For example, if administered to a patient completely lacking α_2M function, an anti-LRP-Aβ molecule would *replace* α_2M function; if administered to a patient exhibiting impaired α_2M function, the same molecule would *supplement* α_2M function. *See* specification at page 39, lines 7-10. A search for molecules that replace α_2M function would therefore necessarily encompass a search for molecules that supplement α_2M function, and vice versa. Thus, it would not entail a "serious burden" on the part of the Examiner, *see* M.P.E.P. § 803, to examine the claims of at least groups I and II together.

In view of the foregoing, Applicants respectfully request that the present restriction requirement, at least with respect to the division of claims 2-10, 12, 13 and 27-29 into groups I, II and III, be reconsidered and withdrawn.

It is not believed that extensions of time are required beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Consideration and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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